INTERIM REPORT of the OPTN/UNOS ORGAN PROCUREMENT ORGANIZATION COMMITTEE

Conference Call on January 27, 2012

1. Imminent and Eligible Death Data Definitions

The Committee reviewed the public comments received on this proposal that was distributed for public comment on September 16, 2011. Prior to the call UNOS staff and committee leadership drafted committee responses that would serve as a basis for the discussion. (*Exhibit A*) Upon review of the committee responses, the committee agreed to the following:

- Change under each organ system "deemed suitable for transplant unless" to "deemed to meet the eligible data definition for a (specify organ) donor unless the donor has the following:"
- Recommend a less than 60 years of age cut off to meet the eligible data definition for a heart donor.
- Recommend that the body weight remain at 5 kg for the eligible donor definition.
- Recommend an effective date of 90 days following approval by the Board of Directors to provide time for communication and training.
- The subcommittee will draft a list of overall comorbidities and clinical definitions to include in the policy.

2. DCD Model Elements

During the November 27, 2011 conference call, the Committee reviewed comments received regarding the DCD Model Elements proposal. The comments were received shortly before the UNOS/OPTN Board of Directors meeting in November 2011. The Executive Committee directed the OPO Committee to revisit the proposal and distribute it for public comment during the next cycle.

3. VCA Federal Registrations

Comment Sought on Proposed Rule Regarding Vascularized Composite Allografts

The U.S.Department of Health and Human Services (DHHS) has issued a proposed rule to include vascularized composite allografts (VCA) within the definition of organs under the authority of the Organ Procurement and Transplantation Network (OPTN). The proposed rule would also include VCA within the definition of human organs covered by section 301 of the National Organ Transplant Act. DHHS is accepting public comment on this proposed rule through February 14, 2012. (See Exhibit B).

The OPTN requested input from the OPO committee that will be included with the OPTN response to the federal register notice. The Committee's response:

The OPO Committee supports the concept of including vascularized composite allografts (VCAs) within the definition of organs under the authority of the OPTN. The Committee expressed concern about the impact on state first person authorization registries which may not be inclusive for VCA authorization. It is recommended that VCA authorization be required so individuals or family members can be informed and have the option of donating VCAs. It should not be implied that first person authorization to donate organs would include VCAs. This is an issue for the individual states to address, and there might be a need for a grace period to allow state first person authorization registries time to update their processes. Finally, the Committee acknowledged that OPOs will be impacted in the future as more details about procurement, allocation, member requirements, and data submission are developed.

Lori Brigham, MBA, Committee Chair Washington Regional Transplant Community

Robert A. Hunter, MPA UNOS Staff, Policy Analyst

Attendance

Name	Position	January 27, 2012
Lori Brigham, MBA	Committee Chair	X
Richard Pietroski, MS, CPTC	Committee Vice-Chairman	Х
Chris Curran	Region 1 Rep	X
Susan Stuart, RN, MPM	Region 2 Rep	
Christy Corbitt, RN, CPTC	Region 3 Rep	
James Cutler, CPTC	Region 4 Rep	Х
Lisa Stocks, FNP, RN	Region 5 Rep	X
Katharine Kickertz, BSN, CPTC	Region 6 Rep	Х
Meg Rogers	Region 7 Rep	Х
Rob Linderer RN, BSN	Region 8 Rep	Х
Julie Mirkin, MA,RN	Region 9 Rep	X
Paul Nelson, MD, FACS	Region 10 Rep	
Cynthia Willis	Region 11 Rep	X
Sean Van Slyck, BA, CPTC	At Large	Х
Richard Padula, CPTC	At Large	X
William Reitsma, BSN	At Large	Х
Esther Carmichael	At Large	X
Jacqueline Honig, MD	At Large	
Meredith Harrison	At Large	
Teresa Beigay, DrPH	HRSA	X
Robert Walsh	HRSA	X
Bertram L. Kasiske, MD, FACP	SRTR	X
Jon Snyder, PhD, MS	SRTR	X
Tabitha Leighton	SRTR	X
Robert Hunter	UNOS, Committee Liaison	Х
John Rosendale	UNOS, Senior Biostatistician	Х
Pamela Saunders Moore	UNOS, Policy Coordinator	X
Amy Pugh	UNOS, Assistant Director, OPTN Contract Management	Х